II. 510(k) SUMMARY

JAN 8 2002 K011855

Submitted By:

Wampole Laboratories
P.O. Box 1001
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Cranbury, NJ 08512

Contact Person

Maureen Garner
Manager, Regulatory Affairs
Carter Wallace
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Date Prepared:

June 11, 2001

Proprietary Name:

Wampole™ HS-CRP ELISA

Common Name:

C-reactive protein test

Predicate Device:

Dade Behring N High Sensitivity CRP.
510(k) Document Control Number: K991385

Description of Device:

The Wampole™ HS-CRP ELISA is a Class II *in vitro* medical diagnostic device that utilizes conventional enzyme-linked immunosorbent assay technology to quantitatively measure the level of C-reactive protein (CRP) in a serum or plasma specimen.

The assay kit consists of plastic microwell strips, containing adsorbed monoclonal anti-CRP antibody. CRP in the specimen is captured by the immobilized antibody, forming immobilized immune complexes. After washing away excess specimen, polyclonal anti-CRP antibody that has been conjugated to horseradish peroxidase is added, forming a "sandwich" of monoclonal antibody, CRP antigen, and conjugated polyclonal antibody. After washing, the immobilized CRP sandwich is exposed to tetremethlybenzidine (TMB), a chromogenic substrate that turns from clear to blue in the presence of peroxidase reaction products. The peroxidase reaction is stopped by the addition of dilute sulfuric acid, which also changes the color of the solution from blue to yellow. The optical density of the yellow end product is directly proportional to the amount of bound CRP antigen, and is quantitated on an ELISA reader at 450 nm. Specimen CRP levels are then determined by interpolation from a standard curve of optical density versus CRP concentration.

II. 510(k) SUMMARY (cont'd)

Intended Use of the Device:
The Wampole HS-CRP ELISA is an *in vitro* diagnostic enzyme-linked immunosorbent assay (ELISA) intended for the quantitative measurement of C-reactive protein (CRP) levels in human serum and plasma. CRP measurements aid in the evaluation of the extent of injury to body tissues.

Technological Characteristics:
The Wampole HS-CRP ELISA uses conventional "microwell" technology, is similar in technology to other "sandwich" ELISA devices and it has the same characteristics and intended use as the predicate device. Other devices include those that detect circulating levels of lipoproteins or human chorionic gonadotropin (hCG). The Wampole HS-CRP ELISA has the same technological features, characteristics and intended use as the predicate device. The monoclonal and polyclonal antibodies used, as well as the recombinant standard antigen, all are derived from established technology. The colored end product is read on standard ELISA readers, which use monochromatic filters of wavelengths pre-selected for specific substrates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 3 2002

Ms. Maureen N. Garner
Director, Regulatory Affairs
Carter-Wallace, Inc.
Wampole Laboratories Division
P.O. Box 1001
Half Acre Road
Cranbury, NJ 08512

Re: k011855
Trade/Device Name: Wampole HS-CRP ELISA
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: October 30, 2001
Received: October 31, 2001

Dear Ms. Garner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE STATEMENT

510(k) Number: K011855

Device Name: Wampole HS-CRP ELISA

Indications for Use: The Wampole HS-CRP ELISA is an *in vitro* diagnostic enzyme-linked immunosorbent assay intended for the quantitative measurement of C-reactive protein (CRP) levels in human serum and plasma. CRP measurements aid in the evaluation of the extent of injury to body tissues.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011855

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Precription Use ✓ -OR- Over-The-Counter Use _____ (per 21 CFR 801.109)